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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/428,674      | 10/27/1999  | MICHAEL NEHLS        | 8535-029-999        | 4973             |

20583            7590            06/03/2003  
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NEW YORK, NY 100362711

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| EXAMINER |
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MARSCHEL, ARDIN H

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1631     |              |

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

|  |                                      |                                     |
|--|--------------------------------------|-------------------------------------|
|  | Application No.<br><b>09/428,674</b> | Applicant(s)<br><b>Nehls et al.</b> |
|  | Examiner<br><b>Ardin Marschel</b>    | Art Unit<br><b>1631</b>             |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

1)  Responsive to communication(s) filed on Feb 3, 2003

2a)  This action is FINAL.      2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

4)  Claim(s) 3 and 10-14 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 3 and 10-14 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are a)  accepted or b)  objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved by the Examiner. If approved, corrected drawings are required in reply to this Office action.

12)  The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

13)  Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)  All b)  Some\* c)  None of:

1.  Certified copies of the priority documents have been received.

2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a)  The translation of the foreign language provisional application has been received.

15)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

1)  Notice of References Cited (PTO-892)

4)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_

2)  Notice of Draftsperson's Patent Drawing Review (PTO-948)

5)  Notice of Informal Patent Application (PTO-152)

3)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_

6)  Other: \_\_\_\_\_

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission, filed on 2/3/03, has been entered.

Applicants' arguments, filed 2/3/03, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

**TITLE**

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. Only polynucleotides are presently being claimed whereas, in contrast, the present title includes both polynucleotides as well as polypeptides.

**LACK OF UTILITY**

The pending claims have been reviewed in light of the Utility Examination Guidelines and Guidelines for Examination of Patent Applications under 35 U.S.C. 112, first paragraph,

"Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1092-1111, Friday, January 5, 2001.

The examiner is using the following definitions in evaluating the claims for utility.

"Specific" - A utility that is *specific* to the subject matter claimed. This contrasts with a *general* utility that would be applicable to the broad class of the invention.

"Substantial" - A utility that defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities.

"Credible" - Credibility is assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record that is probative of the applicant's assertions. That is, the assertion is an inherently unbelievable undertaking or involves implausible scientific principles.

"Well-established" - a specific, substantial, and credible utility which is well known, immediately apparent, or implied by the specification's disclosure of the properties of a material, alone or taken with the knowledge of one skilled in the art.

35 U.S.C. § 101 reads as follows:

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent

therefore, subject to the conditions and requirements of this title".

Claims 3 and 10-14 are rejected under 35 U.S.C. § 101 because the claimed invention lacks patentable utility due to its not being supported by a specific, substantial, and credible utility or, in the alternative, a well-established utility.

The claimed subject matter is not supported by either a well established utility or, alternatively, a specific, substantial, and credible utility. The disclosed uses are generally applicable to broad classes of polynucleotide subject matter. In addition, further characterization of the claimed subject matter would be required to identify or reasonably confirm a "real world" use. The examiner does not find an adequate nexus between the evidence of record and the asserted properties of the claimed subject matter. Due to a lack of either an art recognized or a well established utility, the instantly claimed invention is rejected due to also lacking the alternatively required combination of a specific, substantial, and credible utility. Although it may be credible that one or more polynucleotides as claimed are involved in late stages of stem cell differentiation and development, the lack of a specific and substantial utility sufficiently supports this rejection. Applicants have argued that genes as identified by the method disclosed in the instant specification have a well established utility in the art. This

allegation has been argued in the REMARKS, filed 2/3/03, but without any factual support and thus is non-persuasive.

Applicants argue further that genes identified by the instantly disclosed method that are not involved in cell viability are "likely" to be involved in the late stages of stem cell differentiation and development and that the instant method enriches a class of such genes. In response the enrichment of this class is also an allegation without factual support, only further research as to enrichment evaluation may support this. Additionally, applicants' arguments admit of a likelihood of involvement in late stage stem cell differentiation and development whereas an equally likely explanation is that the genes identified by the instant disclosed method are optionally useful genes for a variety of mature cell functions that may or may not be utilized during such mature cell functioning. Again further research is required in order to obtain some type of specific and substantial utility such as being directly and substantially involved in a specific cell differentiation step or stage. Applicants have not set forth any reasoning or arguments or evidence as to whether or not stem cell differentiation or development depends or is directly involved in any claimed polynucleotide. Only a possibility or likelihood is set forth which can only be resolved by further research. Applicants then argue that genetic mapping is facilitated without phenotypic

selection via the instantly disclosed method. Applicants, however, have not set forth what is being mapped regarding a utility, either specific or substantial. Mapping a gene without further research still is deemed reasonably a general property of all genes, all of which may be mapped, but still lacking any specific or substantial utility after knowing where a gene is in a genome, for example. Applicants lastly argue that when genes as instantly identified are assembled onto a microarray that then teratocarcinoma cell differentiation stages are identified. This again is an allegation without factual support and therefore non-persuasive. Since the instantly identified genes have not been correlated or associated by appropriate evidence or reasoning to any particular differentiation stage, only further research will produce such connections, if they even exist. Also, the usage of microarray screening for differentiation stages is clearly further research which has apparently not yet been performed because applicants' arguments are clearly the setting forth of a future research project. In summary, this rejection is based on a lack of specific and substantial utility which thus supports a lack of the combination of specific, substantial, and credible utility although credibility is not an issue as it is deemed credible that one or more genes may be involved in late stage stem cell differentiation and development. The alternative well established utility has also not been met by applicants

disclosure or arguments as discussed above.

Applicant should explicitly identify a well established utility, or, alternatively, a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention.

Claims 3 and 10-14 are also rejected under 35 U.S.C. § 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial, and credible utility or a well-established utility for the reasons set forth above, one skilled in the art would not know how to use the claimed invention.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703) 308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

June 3, 2003

*Ardin H. Marschel*  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER